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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF :  
FLORENCE L'ALLORET, ET AL. : EXAMINER: YOON  
SERIAL NO: 09/903,768 :  
FILED: JULY 13, 2001 : GROUP ART UNIT: 1714  
FOR: NANOEMULSION CONTAINING :  
NONIONIC POLYMERS, AND ITS USES :

DECLARATION UNDER 37 C.F.R. §1.132

COMMISSIONER FOR PATENTS  
ALEXANDRIA, VIRGINIA 22313

SIR:

Now comes Florence L'Alloret who states that:

1. I am an inventor of 09/903,768 and am familiar with the prosecution history thereof.
2. I have been employed by L'Oréal for 6 years as an engineer in the field of skin care formulation.
3. The following experiments were performed by me or under my supervision.
4. The following experiments demonstrate that formulating an oil-in-water nanoemulsion with an oily phase, at least one amphiphilic lipid and at least one water-soluble nonionic polymer results in stable compositions compared to compositions prepared with thickeners such as hydroxymethylpropyl cellulose and Hostacerin AMPS as described in U.S. patent no. 5,925,341 in column 12, lines 34-44.
5. Three compositions were prepared, each having the same ingredients with the exception of the polymer used. In these compositions poly (ethylene oxide) having a molar

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mass of 300,000 g/mol (Example 1) was replaced with hydroxymethylpropylcellulose (Example 2) or Hostacerin AMPS (Example 3). The compositions were prepared and assessed according to the description provided in the present application, e.g., on pages 33-34.

6. The specific formulations for each of these compositions is shown in the Table below. In addition, the amount of each polymer is varied slightly to compensate for the difference in thickening power, but these slight differences have no effect on the outcome of turbidity of the resultant compositions. In addition, triethanolamine was added only to Example 3 simply for neutralizing the anionic Hostacerin AMPS polymer:

Phase	Ingredient	Ex. 1	Ex. 2	Ex. 3
A	Water	48%	48%	48%
	Dipropylene glycol	8 %	8 %	8 %
	Glycerin	4 %	4 %	4 %
B	PEG-400 isostearate	3.6 %	3.6 %	3.6 %
	Acylglutamate 11S21	0.4 %	0.4 %	0.4 %
	Isocetyl stearate	8%	8%	8 %
	Isohexadecane	8 %	8 %	8 %
C	Poly(ethylene oxide) having a molar mass of 300,000 g/mol	3 %	0	0
	Hydroxymethylpropylcellulose (95.5% active material) Methocel F 4M Dow Chemical	0	1.05%	0
	Hostacerin AMPS (Clariant)	0	0	0.26 %
	Triethanolamine	0	0	0.26%
	water	17%	18.95%	19.48%
	Total	100%	100%	100%
	Macroscopic appearance	Transparent	White	White
	Turbidity	composition 288 NTU	composition > 1000 NTU	Composition >1000NTU

7. The resultant compositions are shown in the attached Exhibit 1.

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8. As shown in the attached Exhibit and presented in the above Table, the composition of Example 1 is transparent and has a turbidity of 288 NTU. In contrast, Examples 2 and 3 were white in appearance and had significantly higher turbidities (greater than 1000 NTU).

10. These results show that unlike Examples 2 and 3 in which the thickeners from U.S. 5,925,341 were used, compositions according to the present invention provide thickened nanoemulsions which are transparent and with low turbidity. In addition, I have no reason to believe that the results obtained with poly (ethylene oxide) having a molar mass of 300,000 g/mol as a representative of the water-soluble nonionic polymer would not be similar for other combinations as defined in the claims of the present application.

11. These results are important because they demonstrate that the combination of an amphiphilic lipid, water-soluble nonionic polymer in a oil-in-water nanoemulsion has significant advantages for preparing stable, transparent compositions. As discussed in the above-identified application on page 2, there is a need to be able to thicken nanoemulsions without altering the cosmetic properties of the composition, such as its transparency (page 2, lines 16-28). U.S. 5,925,341 describes in column 12, optional additives, including thickeners and then follows with a discussion of possible thickeners, including cellulose derivatives (hydroxyethylpropylcellulose) and acrylate polymers such as Hostacerin. This patent does not emphasize any importance in selecting water-soluble nonionic polymers as claimed. Therefore, I find that the data presented in the Table above quite surprising in view of the discussion in the U.S. 5,925,341 patent.

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12. That the undersigned petitioner declares further that all statements made herein of his own knowledge are true and that all statements made on information are believed to be true. Further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of this application or any patent issuing thereon.

  
Florence L'Alloret

  
Date